

REMARKS

Claims 1-14 are pending in the present application. Claims 8-11 and 14 have been withdrawn from consideration. Claims 1-7, 12 and 13 are rejected. By virtue of this amendment, claims 3, 4, and 6 have been amended to delete the term "surface". Support for the amendment of claims 3, 4, and 6 is found in the specification on, *inter alia*, page 19, lines 1-6 and Example 2. Claims 1, 2, and 13 have been amended to correct typographical errors.

With respect to all claim amendments and cancellations, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application.

Rejection under 35 U.S.C. § 102(b)

Claims 1-7 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by van Niekerk et al. (Int J Cancer 43, 1989) or Zeihmet et al. (Gynecologic Oncology 62, 1996). The Examiner alleges that Zeihmet and van Niekerk teach isolated cultures of ovarian mesothelial cells. The Examiner contends that although the references don't teach all of the claimed characteristics of the cells, such characteristics would be inherent to the cells as the cell populations are identical, and the references do teach that the cells have the cell markers cytokeratin and vimentin. The Examiner concludes that the references anticipate the claimed subject matter.

Applicants respectfully traverse this rejection.

Applicants respectfully note that claims 1-7 of the present invention are directed to a substantially pure population of human ovarian mesothelial cells wherein said ovarian mesothelial cells have a pluripotent capacity to differentiate into ovary surface epithelial cells or granulosa cells. Applicants also note that mesothelial cells from different human tissue are different types of mesothelial cells. For example, as stated in van Niekerk et al., ovarian

mesothelium is structurally and morphologically different from pelvic and extra-pelvic mesothelium even though they have common embryonic origin because local factors and/or reproductive patterns may play a role in regulating growth and development of the mesothelium.

Page 1065, first paragraph.

The mesothelial cells described by van Niekerk et al. are collected from ascitic fluid from adult patients with ovarian carcinoma or patients with ascites in which no malignant cells were diagnosed. Page 1065, from bottom of column 1 to top of column 2. Applicants respectfully submit that the Examiner has not shown that the mesothelial cells described by van Niekerk et al. are ovarian mesothelial cells of the present invention, much less ovarian mesothelial cells that have a pluripotent capacity to differentiate into ovary surface epithelial cells or granulosa cells.

In the Office Action, the Examiner states that although the references don't teach all of Applicants' claimed characteristics, such markers would be inherent to the cells as the cells populations are identical. According to the Examiner, the claimed cells are inherently disclosed in the cited references.

Applicants respectfully point out that the Examiner has not made a *prima facie* case for inherent anticipation under 35 U.S.C. § 102, and has not provided the required basis for alleging inherent anticipation.

The requirements for a rejection based on inherency are stated in M.P.E.P. § 2112, which describes the Examiner's burden in making such a rejection:

In relying on the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

M.P.E.P. § 2112 (emphasis in original).

Moreover, "the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." Id. (quoting In re Oelrich, 212 USPQ 323, 326 (CCPA 1981)).

The M.P.E.P. is in accordance with well-established case law addressing inherency. To serve as an anticipation when the reference is silent about the asserted inherent characteristic, the missing descriptive matter must be shown to be necessarily present in the thing described in the reference, and that it would be so recognized by the person of ordinary skill in the art. See Continental Can Co. v. Monsanto Co., 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). “Inherency may not be established by probabilities or possibilities,” In re Oelrich, 212 USPQ 323, 326 (CCPA 1981), and “occasional results are not inherent.” Mehl-Biophile Int’l Corp. v. Milgraum, 52 USPQ2d 1303, 1306 (Fed. Cir. 1999).

Accordingly, in order to make a *prima facie* case of inherent anticipation based on van Niekerk et al., the Examiner is required to advance a basis in fact and/or technical reasoning to reasonably support the assertion that mesothelial cells from ascitic fluid are necessarily a substantially pure population of human ovarian mesothelial cells wherein said ovarian mesothelial cells have a pluripotent capacity to differentiate into ovary surface epithelial cell or granulosa cells as claimed in the present invention. One would hardly expect that mesothelial cells from ascitic fluid as described in van Niekerk et al. would necessarily be a substantially pure population of ovarian mesothelial cells further having the characteristics as claimed in the present invention.

By contrast, in the present Office Action, the Examiner does not support the inherency rejections but only provides the conclusory statement that the cells in the cited references are identical to the ovarian mesothelial cells as claimed in the present invention. Applicants respectfully request that the Examiner support this rejection with a basis in fact and/or technical reasoning, as required. In the absence of such evidence, Applicants respectfully request withdrawal of the rejection based on van Niekerk et al.

The mesothelial cells described by Zeihmet et al. are human peritoneal mesothelial cells obtained from omental tissue. Page 384, bottom of second column. Applicants respectfully submit that since the mesothelial cells described are not ovarian mesothelial cells of the present invention, Zeihmet et al. do not anticipate the claims of the present invention. The above

discussion regarding the inherency rejection applies equally here. Applicants respectfully request that the Examiner provide factual support that human peritoneal mesothelial cells described in Zeihmet et al. are necessarily identical to the ovarian mesothelial cells as claimed in the present invention. In the absence of such evidence, Applicants respectfully request withdrawal of the rejection based on Zeihmet et al.

In view of the above, Applicants respectfully request the rejection be withdrawn.

Rejection Under 35 U.S.C. § 103(a)

Claims 12 and 13 stand rejected under 35 U.S.C. § 103 as being allegedly obvious over van Niekerk et al. (Int J Cancer 43, 1989) or Zeihmet et al. (Gynecologic Oncology 62, 1996). The Examiner contends that it would have been obvious at the time the invention was made to use the cells of the two references in assays determining the effects of substances on said cells or to isolate and use the cellular products of the cells because these are obvious uses and utilities of isolated cells/cell lines and these methods are well known applications of cells.

Applicants respectfully traverse this rejection.

As discussed above, neither van Niekerk et al. nor Zeihmet et al. teach ovarian mesothelial cells as claimed in the present invention, and the Examiner has provided no basis for the statement that these references inherently teach the claimed cells.¹ Thus, van Niekerk et al. or Zeihmet et al. do not teach each and every aspect of the claimed invention. Applicants respectfully submit that the Examiner has not set forth a *prima facie* case of obviousness.

Applicants respectfully request that this rejection be withdrawn.

¹ Further, even if these references inherently taught the claimed cells (which Applicants contend they do not), such inherency is an improper basis for an obviousness rejection.



CONCLUSION

Applicants have, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**".

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **415072000600**.

Respectfully submitted,

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By:


Jie Zhou
Registration No. 52,395

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5922
Facsimile: (650) 494-0792



VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend claims 1-4, 6, and 13 as follows:

1. (Amended) A substantially pure population of human ovarian mesothelial cells wherein said ovarian mesothelial cells have a pluripotent capacity to differentiate into ovary surface epithelial [cell] cells or granulosa cells.
2. The ovarian mesothelial cells according to claim 1, wherein said ovarian mesothelial cells maintained in nutrient media retain the pluripotent capacity to differentiate into ovary surface epithelial [cell] cells or granulosa cells.
3. (Amended) The ovarian mesothelial cells according to claim 1, wherein said ovarian mesothelial cells are identifiable by the expression of at least one cell [surface] marker.
4. (Amended) The ovarian mesothelial cells according to claim 3, wherein said cell [surface] marker is a cytokeratin.
6. (Amended) The ovarian mesothelial cells according to claim 5, wherein said ovarian mesothelial cells further express vimentin as a cell [surface] marker.
13. (Amended) A method of providing a source of nucleic acids or proteins in a development of bioassays comprising isolating nucleic acids or proteins from the human ovarian mesothelial cells as recited in claim 1 and using said nucleic acids or proteins as one or more of the [principle] principal component in the bioassays.